Complete Summary

GUIDELINE TITLE

Guidelines of care for primary cutaneous melanoma.

BIBLIOGRAPHIC SOURCE(S)

Guidelines of care for primary cutaneous melanoma. J Am Acad Dermatol 2001 Oct;45(4):579-86. [44 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Primary cutaneous melanoma

Note: This guideline does not address primary melanomas in less common sites, such as the nail unit and the mucous membranes.

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Oncology
Pathology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To address the management of those patients with a primary cutaneous melanoma lesion who do not have clinical or histological evidence of regional or metastatic disease.

TARGET POPULATION

Patients with a primary cutaneous melanoma lesion who do not have clinical or histological evidence of regional or metastatic disease.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. History and physical (complete skin exam including lymphatics)
2. Biopsy:
    - Excision of lesion with narrow margins
    - Incisional biopsy when suspicion for melanoma is low, the excision is large, or when impractical to perform an excision
    - Repeat biopsy if initial biopsy specimen is inadequate for accurate histologic diagnosis or staging.
3. Histologic evaluation

Treatment/Management

1. Surgical excision
2. Staging of asymptomatic patients
3. Patient education on self-examination and lymph nodes
4. Routine follow-up (at least annually)

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality
- Local recurrence of melanoma
- Detection of occult metastatic disease
- Prognostic value of histologic characteristics
- Survival
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Task Force employed an evidence-based model and performed a comprehensive literature search of English language articles and articles with English language abstracts.

NUMBER OF SOURCE DOCUMENTS

The number of source documents include all those that were reviewed and documented in the guideline technical report. The total count is 720. The technical report describes whether the review was full-text, abstract or title.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence Rating (See following Criteria)

Strong: Based on high quality scientific evidence

Moderate: Based on good quality scientific evidence

Expert opinion: Based on limited scientific evidence and Task Force opinion

Clinical Option: Intervention that the Task Force failed to find compelling evidence for or against and that a reasonable provider might or might not wish to implement

Level of Evidence Criteria

Attributes of Study on Diagnosis

1. Good diagnostic test
2. Good diagnostic criteria
3. Test and criteria reproducible
4. Proper patient selection
5. At least 50 cases and 50 controls

Level 1 = all attributes 1-5; Level 2 = 4 of the 5 attributes; Level 3 = 3 of the 5 attributes; Level 4 = 2 of 5 attributes; Level 5 = 1 of 5 attributes
High quality evidence = Levels 1 and 2
Good quality evidence = Level 3
Limited evidence = Levels 4 and 5

Attributes of Study on Prognosis

1. Cohort
2. Good inclusion/exclusion criteria
3. Follow-up of a least 80%
4. Adjustment for confounders
5. Reproducible outcome measures

Level 1 = all attributes 1-5; Level 2 = attribute 1 + any 3 of attributes 2-5; Level 3 = attribute 1+ any 2 of attributes 2-5; Level 4 = attribute 1 + any 1 of attributes 2-5; Level 5 = attribute 1 and no other attributes; Level 6 = none of the attributes.
High quality evidence = Levels 1 and 2
Good quality evidence = Levels 3 and 4
Limited evidence = Level 5

Levels of Evidence of Studies on Treatment and Prevention

1. Several randomized controlled trials (RCTs) that demonstrate a significant difference
2. A randomized controlled trial that demonstrates a significant difference
3. A randomized controlled trial showing some difference
4. A nonrandomized controlled trial or subgroup analysis of a randomized controlled trial
5. A comparison study with some kind of control/comparison
6. Case series without control
7. Case report with <10 patients

High quality evidence = Levels 1, 2, or 3
Good quality evidence = Levels 4 or 5
Limited evidence = Levels 6 or 7

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Prior to the completion of the literature review and the evidence ratings, each issue identified in Section II of the original guideline was assigned to one or two task force members. The members were asked to develop a brief narrative on the issue and to make recommendations based on literature of which they were already aware and on their expert opinion. Subsequent to the literature search and evidence rating, these recommendations were entered on Form 3 (see the

original guideline companion technical report) with an "X" to indicate the quality of the evidence. The forms and the evidence tables were sent to the task force members with instructions to rate each recommendation as described on the form. A modified Delphi technique was used to generate consensus on the recommendations. Two Delphi rounds were conducted, followed by a phone conference in which outstanding issues were discussed. The task force agreed that the guideline would address primary cutaneous melanoma, regardless of lesion thickness, rather than limiting to the American Joint Committee on Cancer (AJCC) stages 0-II. A draft was prepared and distributed to task force members for their approval prior to sending the draft to expert reviewers.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are based on:

Unanimous task force opinion supported by strong to moderate levels of evidence

Majority task force opinion supported by strong to moderate levels of evidence

Unanimous task force opinion supported by limited or weak scientific evidence

Majority task force opinion supported by limited or weak scientific evidence

Unanimous task force opinion only

Majority task force opinion only

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft guideline was submitted to an extensive review process, in accordance with the Administrative Regulations for the Guidelines/Outcomes Committee of the American Academy of Dermatology (AAD). This process includes the opportunity for review and comment by the entire Academy of Dermatology membership, followed by final review and approval by the Academy of Dermatology Board of Directors. See the guideline technical report (Chuang TY, Lowery BJ, Holloway V, Farmer ER. Guidelines of care for primary cutaneous melanoma. Technical report. Schaumburg, IL: American Academy of Dermatology, 2001) for a detailed description of the review process.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The following provides a summary of the recommendations presented in the guideline document. The reader is directed to the original guideline document for a discussion of the rationale for each of the following recommendations.

The levels of evidence (L1-L5), and strength of recommendation ratings are defined after the "Major Recommendations." Citations in support of individual recommendations are identified in Table 1 of the original guideline document.

Biopsy technique and histologic evaluation

1. Whenever possible excise the lesion with narrow margins for diagnostic purposes.
   Level of Evidence: L1 (head and neck only)
   Strength of Recommendation: Unanimous Task Force opinion and strong evidence head and neck only.
2. An incisional biopsy technique is appropriate when the suspicion for melanoma is low, the lesion is large, or when it is impractical to perform an excision.
   Level of Evidence: L1/2
   Strength of Recommendation: Unanimous task force opinion and strong evidence.
3. Perform a repeat biopsy if the initial biopsy specimen is inadequate for accurate histologic diagnosis or staging.
   Strength of Recommendation: Unanimous Task Force opinion.
4. Fine needle aspiration cytology should not be used to assess the primary tumor.
   Level of Evidence: L3 (that can be used for primary)
   Strength of Recommendation: Unanimous Task Force opinion.
5. Histologic interpretation should be performed by a physician experienced in the microscopic diagnosis of pigmented lesions.
   Strength of Recommendation: Majority Task Force opinion.

Pathology Report

1. Include in the biopsy report:
   a. The patient's age and gender, and the anatomic site of the lesion
      Level of Evidence: L1/2
      Strength of Recommendation: Unanimous Task Force opinion and conflicting evidence.
   b. The gross description of the specimen
      Strength of Recommendation: Unanimous Task Force opinion.
   c. The microscopic description of the specimen (may be contained within a traditional microscopic description, a list format, an image format, or incorporated within the microscopic diagnosis)
      Strength of Recommendation: Unanimous Task Force opinion.
   d. The diagnosis
      Strength of Recommendation: Unanimous Task Force opinion.

e. The tumor thickness in millimeters (Breslow's level)
   Level of Evidence: L1/2
   Strength of Recommendation: Unanimous Task Force opinion and strong evidence.
f. Ulceration
   Level of Evidence: L1
   Strength of Recommendation: Unanimous Task Force opinion and strong evidence.
g. Margin involvement for surgical excisions
   Strength of Recommendation: Unanimous Task Force opinion.

2. Reporting of the following histologic features is encouraged, but optional:
   a. Clark's level
      Level of Evidence: L1/2
      Strength of Recommendation: Unanimous Task Force opinion.
   b. Growth phase
      Level of Evidence: L2
      Strength of Recommendation: Unanimous Task Force opinion.
   c. Tumor infiltrating lymphocytes
      Level of Evidence: L1/2
      Strength of Recommendation: Unanimous Task Force opinion.
   d. Mitotic rate
      Level of Evidence: L1/2
      Strength of Recommendation: Unanimous Task Force opinion.
   e. Regression
      Level of Evidence: L1/2
      Strength of Recommendation: Unanimous Task Force opinion.
   f. Angiolymphatic invasion, microsatellitosis, neurotropism, and histologic sub-type
      Strength of Recommendation: Unanimous Task Force opinion.

Surgical management (margins)

Tumor thickness (Recommended clinical excision margins*):

1. in situ lesion (0.5 cm margin)
   Level of Evidence: L6
   Strength of Recommendation: Unanimous Task Force opinion.
2. less than 2 mm lesion (1 cm margin)
   Level of Evidence: L2
   Strength of Recommendation: Majority Task Force opinion and strong evidence.
3. ≥2 mm lesion (2 cm margin)
   Level of Evidence: L1/2
   Strength of Recommendation: Majority Task Force opinion and strong evidence.

* Based on histologic confirmation of tumor free margins

Initial diagnostic work-up (asymptomatic patients) and on-going follow-up

1. Routine laboratory tests and imaging studies are not required in asymptomatic patients with primary cutaneous melanoma ≤4 mm thick for initial staging or routine follow-up. Indications for such studies are directed by a thorough medical history and thorough physical examination. (Chest x-ray and serum lactic dehydrogenase [LDH] are optional)
   Level of Evidence: L1/2
   Strength of Recommendation: Unanimous Task Force opinion and strong evidence.
2. Patient education on self-examination of the skin and lymph nodes is recommended.
   Level of Evidence: L3
   Strength of Recommendation: Unanimous Task Force opinion and moderate evidence.
3. Routine interval follow-up physical examinations are recommended at least annually.
   Level of Evidence: L1/2, L3
   Strength of Recommendation: Unanimous Task Force opinion and strong/moderate evidence.
4. The results of routine interval history and physical examination should direct the need for laboratory tests and imaging studies.
   Strength of Recommendation: Unanimous Task Force opinion.

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CLINICAL ALGORITHM(S)

An algorithm for the diagnosis, treatment, and management of primary cutaneous melanoma is provided.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation. (See â œMajor Recommendationsâ).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved diagnosis and management of primary cutaneous melanoma.
- Reduced morbidity and mortality through the detection of asymptomatic metastases and additional primary melanomas.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

1. Adherence to this guideline will not ensure successful treatment in every situation. Furthermore, these guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient.
2. This guideline reflects the best available data at the time the report was prepared, but caution should be exercised in interpreting the data; the results of future studies may require alteration of the conclusions or recommendations set forth in this report.
3. The value of the sentinel lymph node biopsy is undetermined at this time, and the issue is not addressed in the guideline.
4. The guideline authors refer patients who have symptoms of regional or distant metastases to guidelines for melanoma developed by the Australian Cancer Network and the National Comprehensive Cancer Network.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Guidelines of care for primary cutaneous melanoma. J Am Acad Dermatol 2001 Oct;45(4):579-86. [44 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Mar

GUIDELINE DEVELOPER(S)

American Academy of Dermatology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Dermatology operational funds and member volunteer time supported the development of this guideline.

GUIDELINE COMMITTEE

- American Academy of Dermatology Melanoma Guideline Development Task Force
- American Academy of Dermatology Guidelines/Outcomes Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force: Arthur J. Sober, MD, Chair, Tsu-Yi Chuang, MD, MPH, Madeleine Duvic, MD, Evan R. Farmer, MD, James M. Grichnik, MD, Allan C. Halpern, MD, Vincent Ho, MD, Victoria Holloway, MD, MPH, Antoinette F. Hood, MD, Timothy M. Johnson, MD, Barbara J Lowery, MPH, and the Guidelines/Outcomes Committee*

*Guidelines/Outcomes Committee: Evan R. Farmer, MD, Chair, Abby S. VanVoorhees, MD, Chair-elect, Tsu-Yi Chuang, MD, MPH, Boni E. Elewski, MD, Arnold W. Gurevitch, MD, Robert S. Kirsner, MD, Lawrence M. Lieblich, MD, Marianne N. O'Donoghue, MD, Yves P. Poulin, MD, Barbara R. Reed, MD, Randall K. Roenigk, MD, and Barbara J. Lowery, MPH.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the Guideline. This is the first update of a guideline that was published in 1993 (Drake LA et. al., Guidelines of care for malignant melanoma. J Am Acad Dermatol 1993;28[4]:638-41).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from AAD, PO Box 4014, Schaumburg, IL 60168-4014, (847) 330-0230 ext. 333; Fax (847) 330-1120; Web site, www.aad.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Chuang TY, Lowery BJ, Holloway V, Farmer ER. Guidelines of care for primary cutaneous melanoma. Technical report. Schaumburg, IL: American Academy of Dermatology, 2001.

Electronic copies: Not available at this time.

Print copies: Available from AAD, 930 N. Meacham Road, PO Box 4014, Schaumburg, IL 60168-4014, (847) 330-0230; Fax (847) 330-0050; Web site, www.aad.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 30, 2001. The information was verified by the guideline developer as of May 14, 2001.

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